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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/773,394 01/31/01 WIKLUND

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002352 HM12/0410  
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EXAMINER

BAHAR, M

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/773,394

Applicant(s)

WIKLUND ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

***Claim Objections***

Claims 7-12 are objected to because of the following informalities: “dosing rate” in claim 7 would be more clearly restated as the amount of composition/infusion based on recitation of effective amounts, instead of doses, in base claim 1 .

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 15, the expression “an amount effective to preserve skeletal muscle” is indefinite since one of ordinary skill in the art would not know what effective amount is referred to, e.g., the first recited composition, second recited composition or some combination of the two.. Furthermore the skilled artisan would not be able to determine what percentage of the skeletal muscle would this “effective amount” preserve. The expression “the carrier,” in claims 16 and 17 is indefinite since it is unclear to which of the two carriers recited in claim 15 it refers.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A “combination” as recited in claims 15-19 is non-statutory subject matter. The invention intended to be encompassed by these

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claims, e.g., composition or article of manufacture, is unclear. However, in order to expedite prosecution the "combination" in claims 15- 19 herein has been treated as being drawn to a composition.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Veech (USPN 5,719,119).

Veech (USPN 5,719,119) teaches that normal plasma contains concentrations of ammonium ions x [alphaketoglutarate]/[glutamate]. Veech also teaches alpha ketoglutarate and ammonium in an amino acid solution containing glutamate which can control the redox state of the mitochondria, see col. 13 line 66 to col. 14 line 20. Carriers taught in the reference are useful for infusion or oral compositions. See table 9, and columns 20-21.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (USPN 5,719,119) in view of applicant's admissions in the specification section entitled "Background of the Invention," pages 1-3, particularly page 2.

Veech (USPN 5,719,119) teaches that normal plasma contains concentrations of ammonium ions x [alphaketoglutarate]/[glutamate]. Veech also teaches alpha ketoglutarate and ammonium in an amino acid solution containing glutamate which can control the redox state of the mitochondria and therefore be useful in nitrogen-containing pharmaceutical compositions , see col. 13 line 5 to col. 14 line 20.

Veech (USPN 5,719,119) does not teach the particular salts of ammonium or alpha-ketoglutarate to be used in its solution/composition.

The applicant teaches that Ammonium Chloride is known to be administered to patients in pharmaceutical compositions, see page 2 of the specification.

It would have been obvious to one of ordinary skill in the art at the time invention was made to use the recited salt of ammonium and alpha-ketoglutarate in Veech's solution. One of ordinary skill in the art would have been motivated to use any known pharmaceutically acceptable salts of ammonium and alpha-ketoglutarate since the selection of known pharmaceutically acceptable salts of actives is considered within the skill of the artisan.

Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (USPN 5,719,119).

Veech (USPN 5,719,119) teaches a parenteral nutrition aqueous solution useful for preserving bodily protein stores comprising alphaketoglutarate, glutamine and ammonium in order to increase organ protein content and/or organ functional capacity in trauma or a

postoperative period, see cols. 13, 14, 23 and 24, claim 1, see also col. 6 lines 56-59, see further col. 7, line 64-col. 8 line 7.

Veech (USPN 5,719,119) does not teach the dosing rate of each compound.

It would have been obvious to one of ordinary skill at the time the invention was made to use ammonium and alpha-ketoglutarate in an infusion in the dosing rates provided.

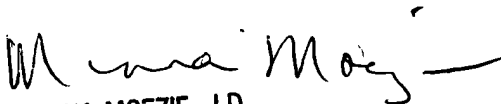
One of ordinary skill in the art would have been motivated to use both ammonium and glutamine in a composition and method of preserving blood glutamine levels and in turn protein catabolism during the postoperative catabolic period since ammonium ions (in an amino acid solution containing glutamate (and alphaketoglutarate optionally) can control the redox state of the mitochondria. Optimization of amounts and dosing rates is within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
April 5, 2001

  
MINNA MOEZIE, J.D.  
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